Approved Patient Information Leaflet for ROCURONIUM FRESENIUS

SCHEDULING STATUS: S4

ROCURONIUM 25 mg/2,5 ml FRESENIUS

ROCURONIUM 50 mg/5 ml FRESENIUS

ROCURONIUM 100 mg/10 ml FRESENIUS

Solution for injection or infusion

Rocuronium bromide

Sugar free.

Read all of this leaflet carefully before you are given ROCURONIUM FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What ROCURONIUM FRESENIUS is and what it is used for
2. What you need to know before you are given ROCURONIUM FRESENIUS
3. How ROCURONIUM FRESENIUS will be administered to you
4. Possible side effects
5. How to store ROCURONIUM FRESENIUS
6. Contents of the pack and other information.

1. What ROCURONIUM FRESENIUS is and what it is used for

ROCURONIUM FRESENIUS belongs to a group of medicines called muscle relaxants.

Normally the nerves send messages to the muscles by impulses. ROCURONIUM FRESENIUS acts by blocking these impulses so that the muscles become relaxed.
When you have an operation, your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation.
ROCURONIUM FRESENIUS may also be used if you are having an anaesthetic to ease the insertion of a tube into your trachea (windpipe) for artificial ventilation (mechanical assistance of breathing).
In the intensive care unit (ICU), ROCURONIUM FRESENIUS may be used for up to three days in adults 18 – 65 years, in mechanical assistance of breathing.

2. What you need to know before you are given ROCURONIUM FRESENIUS

ROCURONIUM FRESENIUS should not be administered:

- to you if you are allergic (hypersensitive) to rocuronium bromide or the bromide ion, or any ingredients of ROCURONIUM FRESENIUS (listed in section 6)
- to newborn babies (0 - 1 months old).

ROCURONIUM FRESENIUS is not recommended for use in mechanical assistance of breathing in children and elderly patients in the intensive care unit (ICU) due to a lack of data on safety and efficacy.

Safety in pregnancy and breastfeeding has not been established (see “Pregnancy, breastfeeding and fertility”).

Warnings and precautions

Tell your doctor or health care provider before being given ROCURONIUM FRESENIUS:
Take special care with ROCURONIUM FRESENIUS:

- if you are allergic to any muscle relaxant
- if you have kidney, a liver or a biliary disease
- if you have heart disease or a disease affecting your blood circulation
- if you have oedema (swelling, for example, in the ankle area)
- if you have a disease affecting the nerves and muscles (neuromuscular diseases, e.g. polio, myasthenia gravis, Eaton-Lambert syndrome)
- if you ever developed a too low body temperature during anaesthesia (hypothermia)
- if you have a history of malignant hyperthermia (sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles)
- if you have fever
- if you have a low calcium level in the blood (hypocalcaemia). An example of a condition that may cause this is where you have received massive transfusions
- if you have a low potassium level in the blood (hypokalaemia). Some causes of this condition may be severe vomiting, diarrhoea or diuretic therapy
- if you have a high magnesium level in the blood (hypermagnesaemia)
- if you have low levels of proteins in the blood (hypoproteinaemia)
- if you suffer from dehydration (you use or lose more fluid than you take in)
- if you have an increased amount of acids in the blood (acidosis)
- if you have an increased amount of carbon dioxide in the blood (hypercapnia)
- if you suffer from excessive loss of weight (cachexia)
- if you are overweight or elderly
- if you have burns.

Other medicines and ROCURONIUM FRESENIUS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important with the medicines listed below:

- Aminopyridine derivatives (used in multiple sclerosis).
- Antibiotics.
- Anti-depressants: medicines used to treat depression (e.g. MAO inhibitors).
- Azathioprine (used for transplant rejection prevention and treatment of auto-immune diseases).
- Calcium chloride.
- Corticosteroids (used for inflammation).
- Diuretics or water pills (medicines which increase the amount of urine).
- Edrophonium (used in muscle conditions).
- Lithium salts (used for certain mental disorders).
- Local anaesthetics (e.g. lidocaine (lignocaine), bupivacaine epidural).
- Medicines used for epilepsy treatment (e.g. phenytoin, carbamazepine).
- Medicines used for the treatment of heart disease or high blood pressure (e.g. quinidine, quinine, calcium channel blocking medicines, adrenergic blocking medicines like beta blockers).
- Medicines used for the treatment of a muscle disease called myasthenia gravis (neostigmine, pyridostigmine).
- Medicines used for the treatment or prevention of a viral infection (protease inhibitors, such as gabexate and ulinastatin).
- Norepinephrine (noradrenaline), a hormone which impacts blood pressure and other body functions.
- Potassium chloride.
- Quinine (used for malaria).
- Some laxatives such as magnesium salts.

- Suxamethonium, a muscle relaxant.
- Theophylline (used for treatment of asthma).
- Vitamin B_1 (thiamine).

You may be given other medicines during the procedure which can influence the effects of ROCURONIUM FRESENIUS. These include certain anaesthetics (e.g. local anaesthetics, inhalational anaesthetics), other muscle relaxants and protamines which reverse the anticoagulant effect (prevention of blood clots) of heparin. Your doctor will take this into account when deciding on a suitable dose of ROCURONIUM FRESENIUS for you.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving ROCURONIUM FRESENIUS.

Pregnancy

The safety of use of ROCURONIUM FRESENIUS in pregnancy has not been established.

ROCURONIUM FRESENIUS may be given during Caesarean section.

Breastfeeding

Do not breastfeed for 6 hours after receiving ROCURONIUM FRESENIUS.

Fertility

No information available.

Driving and using machines

ROCURONIUM FRESENIUS has a major influence on your ability to drive and use machines. Do not drive a car or use potentially dangerous machines during the first 24 hours after full recovery from the effects of ROCURONIUM FRESENIUS.

ROCURONIUM FRESENIUS contains sodium

ROCURONIUM FRESENIUS contains 3,64 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0,18 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How ROCURONIUM FRESENIUS will be administered to you

You will not be expected to give yourself ROCURONIUM FRESENIUS.

ROCURONIUM FRESENIUS will be given to you by your anaesthetist. It is given to you intravenously either as a single injection or as a continuous infusion (over a longer period of time) into a vein.

Your doctor will tell you how long your treatment with ROCURONIUM FRESENIUS will last.

If you have the impression that the effect of ROCURONIUM FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

Your doctor will ensure that you receive the correct dose.

During the surgery the effect of ROCURONIUM FRESENIUS is controlled continuously.

If necessary, additional doses could be administered to you. The dose is adjusted to your needs by your doctor. It depends on many factors, such as medicine interactions (their cross activity), the estimated length of surgery as well as your age and clinical condition.

If you receive more ROCURONIUM FRESENIUS than you should

Since a health care provider will administer ROCURONIUM FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage. Your doctor will carefully monitor you while you are treated with ROCURONIUM FRESENIUS, therefore it is unlikely that you will be given too much ROCURONIUM FRESENIUS. If it happens, your anaesthetist will make sure that anaesthesia and artificial ventilation will be continued until you breathe on your own.

If a dose of ROCURONIUM FRESENIUS is missed

Since a health care provider will administer ROCURONIUM FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

ROCURONIUM FRESENIUS can have side effects.
Not all side effects reported for ROCURONIUM FRESENIUS are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while receiving ROCURONIUM FRESENIUS, please consult your health care provider for advice.

If any of the following reactions happen to you, tell your doctor immediately:

Hypersensitivity reactions (allergic reactions) which may be life-threatening. A hypersensitivity reaction may include rash, difficulty in breathing or swelling of the face, lips, throat and tongue.

These are all very serious side effects. If you have them, you may have had a serious reaction to ROCURONIUM FRESENIUS. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

Less frequent side effects:

- Pain at the injection site, reaction at the injection site.
- Medicine ineffective, decreased or increased medicine effect.
- Increased level of histamine in the blood.
- Increase in heart rate (tachycardia).
- Low blood pressure (hypotension).
- Itching or rash.
- Widespread, severe rash (exanthema).
- Welts or hives (urticaria).
- Prolonged effect of muscle relaxation (prolonged neuromuscular block).
- Delayed recovery from anaesthesia. Airway complication of anaesthesia.
- Unpredictable frequent swelling of cutaneous and mucosal tissues such as lips, eyes, oral cavity, larynx, and gastrointestinal system (angioneurotic oedema).
- Loss of movement (paralysis).
- Failure of circulation (circulatory collapse and shock).
- Flushing.
- Breathing (respiratory) failure.
- Stop breathing (apnoea).
- Wheezing (bronchospasm).
- Muscle weakness, which may be worse if you have been treated with corticosteroids. See “Other medicines and ROCURONIUM FRESENIUS”.

- Sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles (malignant hyperthermia).

Side effects with an unknown frequency:

- Kounis syndrome (symptoms such as chest pain relating to reduced blood flow to the heart).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Health care providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**Adverse Drug Reaction Reporting Form**" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ROCURONIUM FRESENIUS.

5. How to store ROCURONIUM FRESENIUS

Store all medicines out of reach of children.

Do not use ROCURONIUM FRESENIUS after the expiry date which is stated in the label and carton.

Store in a refrigerator (2 °C - 8 °C). Protect from light.

The product should be used immediately after opening the vial.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ROCURONIUM FRESENIUS contains

The active substance is rocuronium bromide.

Each 1 ml of solution contains 10 mg rocuronium bromide.

The other ingredients are sodium acetate trihydrate, sodium chloride, glacial acetic acid (for pH-adjustment) and water for injections.

Sugar free.

What ROCURONIUM FRESENIUS looks like and contents of the pack

A clear, colourless to pale brownish-yellow solution.

ROCURONIUM 25 mg/2,5 ml FRESENIUS: 2,5 ml solution in a clear glass vial with a chlorobutyl rubber stopper and an aluminium cap.

5, 10 or 12 vials are packed into an outer carton.

ROCURONIUM 50 mg/5 ml FRESENIUS: 5 ml solution in a clear glass vial with a chlorobutyl rubber stopper and an aluminium cap.

5, 10 or 12 vials are packed into an outer carton.

ROCURONIUM 100 mg/10 ml FRESENIUS: 10 ml solution in a clear glass vial with a chlorobutyl rubber stopper and an aluminium cap.

5, 10, 12 or 20 vials are packed into an outer carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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ROCURONIUM 100 mg/10 ml FRESENIUS:46/17.1/0062

Access to the corresponding Professional Information

The Professional Information is printed and packed with the product.